SOP 1.4.3 **Research Involving Prisoners**

General Description:

Research activities at GMU involving humans must undergo some level of ethical review by the IRB office or the IRB. Per the federal regulations, at 45 CFR 46, prisoners are considered a vulnerable population and research involving prisoners as participants requires additional considerations or protections.

Prisoner is defined in the regulations as any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Minimal risk for prisoners is defined by the regulations as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives or in the routine medical, dental, or psychological examination of healthy persons.

Policy:

1. Research involving prisoners does not qualify for an exempt determination and must be reviewed by the IRB.
2. At least one voting member of the IRB must be a prisoner representative with appropriate background and experience to serve in that capacity.
3. For research involving prisoners, the IRB applies 45 CFR 46 Subpart C to studies. Under Subpart C, the IRB must review and approve the research under 45 CFR 46.305 and determine that the proposed research falls within the categories permissible under 45 CRF 46.306(a)(2), which include the following:
    a. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
    b. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
    c. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or
    d. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of the intent to approve such research.

4. Most research involving prisoners requires review by the full IRB at a convened meeting. Research involving prisoners that is no more than minimal risk and involves only interactions or use/analysis of prisoner data may be reviewed using the expedited procedure. If the project meets the criteria for expedited review, the prisoner representative will review the research.
5. Review of minor modifications to approved research and continuing review of research via the expedited review procedure may involve review by the prisoner representative but this is not always required.

Procedures:

1. If a research project involves prisoners as participants, researchers must include this information in the applicable sections of the IRB application and complete Addendum B (Prisoners).
2. The IRB will review the protocol in accordance with 45 CFR 46 Subpart C. The IRB checklist for research involving prisoners will be completed by the IRB which will ensure that regulatory requirements for research involving prisoners have been met.
3. The IRB will otherwise follow regular procedures for expedited or full board review as necessary.
4. For federally funded research involving prisoners, the institution(s) engaged in the research must certify to the Secretary of Health and Human Services (through OHRP) that the IRB reviewed the research and made seven findings as required by the regulations (45 CFR 46.305(c) and 46.306(a)(1)). Research involving prisoners may proceed only after receipt of the OHRP authorization letter. If OHRP determines that the proposed research does not involve one of the permissible categories, it will state in the letter to the institution that such research involving prisoners cannot proceed.
5. If a researcher learns that a participant in a research study has become incarcerated during the course of a study that did not intend to recruit prisoners, it is the responsibility of the PI to promptly notify the IRB to discuss how this should be handled (for example, the protocol may be re-reviewed according to subpart C or the participant who has become incarcerated may be withdrawn from the research).

Related Forms, Guidance, and SOPs:

- 45 CFR 46 Subpart C
- Prisoner research FAQs
- IRB application addendum B -- Prisoners
- 2.5.1 Full board review
- 2.5.2 Exempt and expedited

Responsibility:

Principal Investigators
Research Team Members
IRB staff
Institutional Review Board

Approval and Version History:

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

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Approved By	Title and Division	Date Approved
Aurali Dade	Associate Vice President, Research Development, Integrity and Assurance	May 24, 2017
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